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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,258	04/03/2001	Sita R. Kaura	65,409-001	2051

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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
07/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/825,258	KAURA, SITA R.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18,23-30 and 32-62* is/are pending in the application.

4a) Of the above claim(s) *16-18,30 and 32-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-15, 23-29, and 49-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-10-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/27/2006 and 5/24/2007 have been entered.

Claims 49-62 have been added.

Claims 14-18, 23-30 and 32-62 are pending.

Claims 16-18 and 36-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4, received December 10, 2001.

Claims 30, and 32-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4 received December 10, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "the adrenergic bronchodilator including an immediate release portion and an extended release portion" recited in claims 49 and 61 renders the claims indefinite because it is not clear how a single chemical compound (adrenergic bronchodilator) would have two portions, i.e., immediate release and extended release, as recited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-15, 23-29, and 49-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlen et al. (WO 97/28797) in view of Katzung ("Basic & Clinical Pharmacology", 6th ed., 1995, page 312-314), both references of record, and Spector et al. (J. Allergy Clin. Immunol., 1995; 96(2):174-181).

Dahlen et al. teaches an asthma treating composition comprises Loratadine and Montelukast sodium (See particularly page 5, Example, whole page).

Dahlen does not expressly teach the asthma treating composition contains a adrenergic bronchodilator such as albuterol. Dahlen does not expressly teach the asthma composition containing cetirizine.

Katzung teaches that albuterol is useful in treating asthma (See particularly page 314, col. 1, first paragraph).

Spector et al. teaches cetirizine is effective in treating mild-to-moderate asthma due to its significant bronchodilatory effect (See particularly the abstract).

It would have been obvious to one skill in the art when the invention was made to incorporate albuterol into the asthma treating composition of Dahlen et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute cetirizine for loratadine in composition of Dahlen et al.

One of ordinary skill in the art would have motivated to incorporate albuterol into the asthma treating composition of Dahlen et al. because combining agents which are known to be useful to treat asthma individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980). One of ordinary skill in the art would have been motivated to substitute cetirizine for loratadine in composition of Dahlen et al. because both cetirizine and loratadine are both antihistamine agent and both are known to be useful in asthma treating composition. Therefore, substituting any known asthma treating antihistamine compounds, including cetirizine, for loratadine would have been reasonably expected to be useful in formulating a composition useful for treating asthma.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, no data was disclosed in the instant specification. Therefore, unexpected benefits are not seen to be present herein.

Response to Arguments

Applicant's arguments filed October 20, 2005 averring the cited prior art's failure to provide suggestion or motivation to combine the teachings to arrive at the instant composition have been fully considered but they are not persuasive. The examiner notes that the basis to combine the herein claimed components into a single composition resides on the fact that they are known to be useful to treat asthma. Therefore, combining the herein claimed agents into a single composition useful for the very same purpose, i.e., treating asthma, would be *prima facie* obvious, absent evidence to the contrary.

Applicant's arguments filed October 20,2 005 averring the lack of basis to support the interchangeability between loratadine and cetirizine have been considered, but are not found persuasive. It is clear from the art that both agents are antihistamine

and are both useful in treating asthma. Therefore, they are functional and therapeutically equivalent. Substituting one for the other would be obvious, absent evidence to the contrary. No such evidence is seen to be present.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SAN-MING HUI
PRIMARY EXAMINER

San-ming Hui
Primary Examiner
Art Unit 1617